REMARKS

I. Status of Claims

Claims 8-26, 30, and 31 are pending in this application.

In the present Amendment, paragraph [007] of the specification has been amended to correct a clear transposition error. Claims 1-7 and 27-29 have been cancelled without prejudice or disclaimer. New claims 30 and 31 have been added. Support for the new claims 30 and 31 can be found in the originally-filed specification and claims, for example, original claims 25 and 26.

Further, claims 8-15 and 17-24 have been amended. Support for the amendments can be found in the originally-filed specification and claims.

Specifically, in claims 9 and 17, two additional provisos are added, which do not constitute new matter for at least the following reason.

"It is for the inventor to decide what *bounds* of protection he will seek." *In re Johnson*, 194 USPQ 187, 196 (CCPA 1977) (emphasis in original). In *In re Johnson*, the appellants amended claim 1 by adding provisos excluding certain species from the genus as originally claimed. *Johnson*, 194 USPQ, at 191. The court held that a limitation provisoing out the members of a genus originally described in the specification can be sufficiently supported by the original specification that taught the entire genus, because the "specification, having described the whole, necessarily described the part remaining." *Id.* at 196. Therefore, the appellants "are not creating an 'artificial subgenus' or claiming 'new matter.'" *Id.*

Similar to *Johnson*, the provisos added in claims 9 and 17 of the present invention limit rather than expand the scope of the invention, by excluding certain

species of the compound of formula (I) that are disclosed in the originally-filed specification. Therefore, as the court explained in *In re Johnson*, such an amendment has sufficient support in the originally-filed application and does not introduce new matter.

Further, the recited compounds of formula (I) in claims 10-15 and 18-23 are the same as those recited in the original claims 2-7.

Therefore, Applicants have not introduced any new matter by the amendments, nor are any estoppels intended thereby.

II. Double Patenting Rejection under 35 U.S.C. § 101

The Examiner provisionally rejects claims 1-8 and 27-29 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-8 and 26-28 of co-pending Application No. 10/715,556 ("the co-pending '556 application"). Office Action, page 2.

Claims 1-7 and 27-29 have been canceled, rendering this rejection of claims 1-7 and 27-29 moot.

Further, Applicants respectfully disagree and traverse the rejection of claim 8 under 35 U.S.C. § 101 as claiming the same invention as that of claim 8 of the co-pending '556 application for at least the following reason.

The M.P.E.P. clearly instructs that "35 U.S.C. 101 prevents two patents from issuing on the same invention. 'Same invention' means identical subject matter." M.P.E.P. § 804 II.A. (citations omitted). Not all compounds recited in claim 8 of the present application are identical to those recited in claim 8 of the co-pending '556 application. Thus, claim 8 of the present application does not claim the same invention

as that of claim 8 of the co-pending '556 application. Accordingly, this rejection of claim 8 is improper.

Applicants respectfully request this rejection be withdrawn.

III. Rejection under 35 U.S.C. § 102(b)

The Examiner rejects claims 1-7 and 27-29 under 35 U.S.C. § 102(b) as being anticipated by WO 99/44995 to Yoshizaki et al. ("*Yoshizaki*"). Office Action, page 3. Applicants respectfully disagree and traverse this rejection for at least the following reason.

Claims 1-7 and 27-29 have been canceled, rendering this rejection moot. Therefore, Applicants respectfully request this rejection be withdrawn.

IV. Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 17-26 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Office Action, page 3. Specifically, the Examiner alleges that "the specification, while being enabling for the treatment of cranial and spinal traumas and peripheral neuropathies, obesity, types II diabetes, atherosclerotic cardiovascular diseases, essential hypertension, [and] polycystic ovary syndrome, does not reasonably provide enablement for the rest of the diseases," *i.e.*, neurodegenerative diseases, strokes, metabolic diseases, syndrome X, and immunodeficiency, as recited in, for example, claim 17. *Id.* at pages 3-4. The Examiner further alleged that, by analyzing each Wands factor, one of ordinary skill in the art would not be able to practice the presently claimed invention without undue experimentation. *Id.* at pages 4-17. Applicants respectfully disagree and traverse this rejection for at least the following reasons.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." M.P.E.P. § 2164.01. Further, "if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate." *Id.* § 2164.02.

Here, the originally-filed specification clearly indicates that "[i]t is known from literature that in the case of metabolic diseases such as diabetes or neurodegenerative diseases such as Alzheimer's disease, there is a connection between the therapy of said diseases and the inhibition of [the kinase] GSK-3β or the phosphorylation of the tau-protein." Specification, paragraph [004] (citation omitted); paragraphs [0150]-[0151]. Further, one of ordinary skill in the art knows that strokes, syndrome X, and immunodeficiency may also result from an abnormal activity of kinases, such as an abnormal activity of the kinase GSK-3β. Therefore, if a compound shows an inhibitory effect on the kinase GSK-3β or the phosphorylation of the tau-protein, one of ordinary skill in the art would reasonably believe that it can be used for the treatment of neurodegenerative diseases, strokes, metabolic diseases, syndrome X, and immunodeficiency, based on the information known in the art.

As shown under "Tau-phsophorylation" and "GSK-3β" in paragraphs [0306]-[0310] of the originally-filed specification, the inventive compounds showed potency of inhibiting the phosphorylation of the tau-protein or the kinase GSK-3β as indicated by the IC_{50} values. Therefore, contrary to the Examiner's allegation, the specification has demonstrated that, coupled with the information known in the art, one of ordinary skill in

the art could use the presently claimed compounds for treatment of neurodegenerative diseases, strokes, metabolic diseases, syndrome X, and immunodeficiency, without undue experimentation.

As the Examiner has failed to point to any evidence rebutting the correlation between the treatment of neurodegenerative diseases, strokes, metabolic diseases, syndrome X, and immunodeficiency and the inhibition of the kinase GSK-3β or the phosphorylation of the tau-protein, this rejection is improper.

In addition, because of the correlation between the treatment of neurodegenerative diseases, strokes, metabolic diseases, syndrome X, and immunodeficiency and the inhibition of the kinase GSK-3β or the phosphorylation of the tau-protein which is known in the art, Applicants respectfully disagree with the Examiner's analysis on the Wands factors for determining whether undue experimentation is necessary to practice the presently claimed invention.

Applicants respectfully submit that the "quantity of experimentation necessary" is limited to the number of assays to be conducted to show the inhibition of the kinase GSK-3β or the phosphorylation of the tau-protein. The originally-filed specification in paragraphs [0306]-[0310] provides detailed direction and guidance on how to perform the assays to show the inhibition of the kinase GSK-3β or the phosphorylation of the tau-protein.

Further, "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." M.P.E.P. § 2164.01 (citation omitted). Applicants respectfully submit that the assays disclosed in

paragraphs [0306]-[0310] of the originally-filed specification are routine experimentations known in the art.

The originally-filed specification in paragraphs [0306]-[0310] also discloses working examples, showing the inhibitory effects of the inventive compounds on the kinase GSK-3β or the phosphorylation of the tau-protein.

Finally, contrary to the Examiner's allegation, the level of one of ordinary skill in the art is high. The Examiner alleges that "[t]he skill level in this art is too low, because no compound effective against neurodegenerative diseases, strokes, metabolic diseases, syndrome X, immunodeficiency or cancer has ever been found." Office Action, pages 14-16. However, the Examiner apparently confuses the concept of "the level of one of ordinary skill in the art" versus the concept of "the achievement or accomplishment level of one of ordinary skill in the art."

The M.P.E.P. clearly instructs that "[f]actors that may be considered in determining level of ordinary skill in the art include (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." M.P.E.P. § 2141.03.

The educational level of the inventor is high, usually requiring a Ph.D. degree. The type of problems encountered in the art varies but the problems are difficult and the technology is sophisticated. Innovation is slow and the prior art solutions to the problems are limited. Therefore, the level of ordinary skill in the art is high.

Accordingly, Applicants respectfully request this rejection be withdrawn.

V. Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner further rejects claims 1-7 and 9-28 under 35 U.S.C. § 112, second paragraph, as being indefinite. Office Action, page 17. Specifically, the Examiner asserts that the phrase "may in turn be" in defining R and Ar in claim 1 does not have a clear meaning. *Id.* at page 6. Applicants respectfully disagree.

Claims 1-7, 27, and 28 have been canceled, rendering this rejection of these claims moot.

For claim 9-26, however, solely for the purpose of advancing the prosecution, Applicants have amended claims 9-15 and 17-24 to make it clearer. Therefore, in view of the amendments, this rejection is moot. Applicants respectfully request this rejection be withdrawn.

In addition, the Examiner alleges that "it appears that 'at least monosubstituted is referring to C_1-C_6-alkyl' and not to other definitions of R or Ar." Office Action, page 17. Applicants respectfully disagree.

In claim 9, for example, the term "unsubstituted or at least monosubstituted" defines R or Ar and should be read into all of the radicals which follow the term, *i.e.*, R is unsubstituted or at least monosubstituted C_1-C_{10}-alkyl, unsubstituted or at least monosubstituted aryl, unsubstituted or at least monosubstituted aryl-(C_1-C_{10}-alkyl)-, unsubstituted or at least monosubstituted heteroaryl, unsubstituted or at least monosubstituted heteroaryl-(C_1-C_{10}-alkyl)-, unsubstituted or at least monosubstituted heterocyclyl, unsubstituted or at least monosubstituted heterocyclyl-(C_1-C_{10}-alkyl)-, unsubstituted or at least monosubstituted C_3-C_{10}-cycloalkyl, unsubstituted or at least monosubstituted polycycloalkyl, unsubstituted or at least monosubstituted C_2-C_{10}-

alkenyl or unsubstituted or at least monosubstituted C_2-C_{10}-alkinyl; and Ar is unsubstituted or at least monosubstituted aryl or unsubstituted or at least monosubstituted heteroaryl.

Therefore, for the reasons above, Applicants respectfully request this rejection be withdrawn.

VI. Objection

Applicants acknowledge, with appreciation, the indication of allowable subject matter in claim 8, and note that it is objected as based on rejected parent claims. *See* Office Action, page 17. Claim 8 has been amended to be an independent claim. Accordingly, Applicants respectfully request this objection be withdrawn.

VII. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application, and the timely allowance of the pending claims.

If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, the Examiner is invited to call the Applicants' undersigned representative at (202) 408-4218.

If there is any fee due in connection with the filing of this response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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